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Tonix Pharmaceuticals Announces Publication of Paper in Antiviral Research Highlighting the Company's Development of Monoclonal Antibody Therapeutics for Monkeypox and Smallpox

Data Represent Research and Development Work Being Conducted at Tonix's Infectious Disease R&D Center (RDC) in Frederick, Md.

CHATHAM, N.J., Jan. 24, 2023 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the publication of a paper entitled, ***"Development of a rapid image-based high-content imaging screening assay to evaluate therapeutic antibodies against the monkeypox virus,"*** in the journal *Antiviral Research*. The publication describes the development and optimization of two high-content image-based assays that were employed to screen for potential therapeutic antibodies against the monkeypox virus using surrogate poxviruses such as vaccinia virus. The article highlights Tonix's TNX-3400 platform, which includes antibodies to potentially prevent or treat monkeypox and smallpox. The article can be accessed online at <https://pubmed.ncbi.nlm.nih.gov/36592670/>.

"These data represent the first wave of research and development conducted at our Infectious Disease R&D Center (RDC) in Frederick, Md," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "The RDC greatly enhances our ability to advance development of our pipeline of vaccines and therapeutics for infectious diseases. The TNX-3400 platform has promise for preventative and therapeutic monoclonal antibodies to treat monkeypox and smallpox."

"The article describes how we optimized and standardized two high-content high-throughput image-based assays. The first assay was a neutralizing assay which detected viral proteins of vaccinia virus and used the assay to screen a large library of antibodies made against pox viruses. The second assay specifically detected phenotype changes in cells, called syncytia, after infection and protection by therapeutics," said Sina Bavari, Ph.D., Executive Vice President of Tonix Pharmaceuticals and site director of the RDC. A critical component in assessing antibodies during pandemics requires the development of rapid but detailed methods to detect and quantitate the neutralization activity. "The neutralizing assay identified several antibodies with the capacity to protect against vaccinia virus infection. We believe this technology will allow us to identify combination therapies for monkeypox and smallpox viruses which was difficult to achieve before. Furthermore, our data suggest that applying this technology has the potential to increase the throughput of screening novel antivirals to

shorten the discovery time for antivirals.”

About TNX-3400

TNX-3400 is the term for series of monoclonal antibodies which bind to key components of pox viruses such as monkeypox and smallpox and protect cells and tissues from infection with these pandemic causing viruses. These antibodies are being developed as broad-spectrum antipox virus and to potentially prevent or treat monkeypox and smallpox infection.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix’s portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix’s CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix’s lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study launched in the second quarter of 2022 and interim data expected in the second quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix initiated a Phase 2 study in Long COVID in the third quarter of 2022 and expects interim data in the third quarter of 2023. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the first quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the first quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a once-daily formulation of tianeptine being developed as a potential treatment for major depressive disorder (MDD) with a Phase 2 study expected to be initiated in the first quarter of 2023. Tonix’s rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix’s immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the first half of 2023. Tonix’s infectious disease pipeline includes a vaccine in development to prevent smallpox and monkeypox, TNX-801, a next-generation vaccine to prevent COVID-19, TNX-1850, a platform to make fully human monoclonal antibodies to treat COVID-19, TNX-3600, and humanized anti-SARS-CoV-2 monoclonal antibodies, TNX-3800, recently licensed from Curia. TNX-801, Tonix’s vaccine in development to prevent smallpox and monkeypox, also serves as the live virus vaccine platform or recombinant pox vaccine (RPV) platform for other infectious diseases. A Phase 1 study of TNX-801 is expected to be initiated in Kenya in the second half of 2023.

**All of Tonix’s product candidates are investigational new drugs or biologics and have not been approved for any indication.*

This press release and further information about Tonix can be found at

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate,” “expect,” and “intend,” among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission (the “SEC”) on March 14, 2022, and periodic reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

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